

APPLICANT(S): DALTON, James T. et al.  
SERIAL NO.: 10/849,039  
FILED: May 20, 2004  
Page 22

## REMARKS

### Status of Claims

Claims 1-95 are pending in the application. Claims 21-23, 32-34, 38-51, 65-67, 76-78 and 82-95 have been withdrawn from consideration. Claims 10 and 11 have been cancelled. Claims 1-20, 24-31, 35-37, 52-64, 68-75 and 79-81 have been rejected. Claims 1, 12-14, 25-28, 30, 52, 57, 58, 59, 60, 61, 63, 64, 69, 70-72, 74 and 75 have been amended.

Support for the methylated metabolites can be found throughout the specification, for example on page 11 lines 9-10, page 14 lines 9-10, page 16 lines 8-9 and page 27 lines 1-2.

Support for the hydroxylated metabolites can be found throughout the specification, for example on page 10 lines 6-12, page 13 lines 6-12, page 15 lines 11-18, page 26 lines 1-10, page 30 lines 1-9, page 32 lines 3-9 and Example 5 and Figure 12.

Support for the deacetylated metabolites can be found throughout the specification, on page 29 line 10, page 15 lines 6-10 and Example 6.

Support for the aminated metabolites can be found throughout the specification, on page 25 lines 6-11, page 28 lines 21-22, page 29, lines 1-4 and Figure 10.

## CLAIM REJECTIONS

### 35 U.S.C. § 103 Rejections

In the Office Action, the Examiner rejected claims 1-20, 24-31, 35-37, 52-64, 68-75 and 79-81 under 35 U.S.C. § 103(a), as allegedly being rendered obvious in view of combined teaching of Tucker (US 4,636,505) and Miller et al (WO 98/55153).

Applicants protest the impropriety of the rejection.

According to MPEP 706.07:

"In making the final rejection, all outstanding grounds of rejection of record should be carefully reviewed, and any such grounds relied on in the final rejection should be reiterated. They must also be clearly developed to such an extent that applicant may readily judge the advisability of an appeal unless a single previous Office action contains a complete statement supporting the rejection.

APPLICANT(S): DALTON, James T. et al.  
SERIAL NO.: 10/849,039  
FILED: May 20, 2004  
Page 23

However, where a single previous Office action contains a complete statement of a ground of rejection, the final rejection may refer to such a statement and also **should include a rebuttal of any arguments raised in the applicant's reply** [Applicants bolded this section for emphasis]. If appeal is taken in such a case, the examiner's answer **should contain a complete statement of the examiner's position**. The final rejection letter should conclude with Form Paragraph 7.39"

The Examiner failed to address Applicants argumentation with respect to Tucker in the January 16, 2007, Office Action. Based on MPEP 706.07, this is improper. Similarly, the Examiner, in the May 3, 2007 Advisory Action failed to address Applicants argumentation with respect to Tucker or Miller, alone or in combination, failing to render the invention obvious.

Claims 1, 52, 69, and dependents therefrom, recite *metabolites* of the SARM compounds represented by formulas I, II, III, IV, VII, VIII, IX, X, which are methylated, hydroxylated, deacetylated or aminated derivatives of the SARM compounds. The metabolites of compounds of formulas I, II, III, IV, VII, VIII, IX, X, are produced as a result of *in-vivo* metabolic processing of the compounds, to yield, *inter-alia* to yield hydroxylated, deacylated, aminated or methylated forms of the compounds of formulas I, II, III, IV, VII, VIII, IX, X.

Miller does not describe nor provide any foundation for metabolites of such SARMS. Specifically Miller describes radiolabelled SARMS only, and their use in imaging the prostate cancer, alone, with only S-bridged compounds exemplified in this context. It would not be obvious, based on Miller, to obtain claimed metabolites of O-bridged compounds of this invention, as one skilled in the art would not be motivated to obtain unlabelled metabolites to image prostate cancer.

Similarly, Tucker neither describes nor provides any foundation for metabolites of such SARMS. Tucker describes a laundry list of antiandrogenic compounds, with only the process of preparation of S-bridged compounds are exemplified. It would not be obvious based on Tucker that the metabolites of O-bridged compounds have androgenic and anabolic activity.

APPLICANT(S): DALTON, James T. et al.  
SERIAL NO.: 10/849,039  
FILED: May 20, 2004  
Page 24

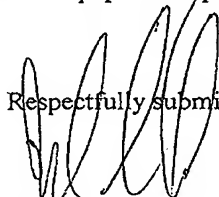
Neither Tucker nor Miller provides any guidance for preparing SARM metabolites. Neither Miller nor Tucker, alone or in combination, lead the skilled artisan to the specific SARM compounds of the formulas I, II, III, IV, VII, VIII, IX, X, possessing anabolic activity. Certainly, neither Tucker nor Miller lead the skilled artisan to the specific metabolites claimed, nor render obvious the O-bridged metabolites including *inter-alia* methylated, hydroxylated, deacetylated, or aminated derivatives of the compounds of formulas I, II, III, IV, VII, VIII, IX, X, as claimed in the present invention. Accordingly, applicants request withdrawal of the rejection.

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,



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